No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing the interests of the generic and biosimilar medicines industry. AAM represents manufacturers and distributors of finished generic and biosimilar pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. Its members provide Americans with generic and biosimilar medicines that are as safe and effective as their brand-name counterparts, but are substantially more affordable. In 2017, generic medicines accounted for roughly 90% of all prescriptions dispensed in the United States but only 23% of total spending. Generic medicines saved patients, taxpayers, and health care payers over $265 billion in 2017 compared to their brand-name counterparts.

AAM seeks to provide courts with the perspective of the generic and biosimilar pharmaceutical industry on important legal issues impacting its members, and to highlight the potential industry-wide consequences of significant pending cases.

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[1] Pursuant to this Court's Rule 37.3(a), counsel for all parties consented to the filing of this brief. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

AAM's members are frequently involved in pharmaceutical patent litigation in which they rely on invalidity defenses such as the on-sale bar. Invalid patents undermine the legitimacy of the patent system, stifle competition, and impede consumers' access to low-cost medicines. AAM members have a significant interest in ensuring that statutory limits to the patent monopoly are enforced according to their terms.

Helsinn and its *amici*'s strained interpretation of the text of § 102(a)(1)—under which the on-sale bar now extends only to sales that are in some way "available to the public" or, as suggested by the United States, made to "an ultimate consumer"—threatens to destabilize the competitive equilibrium contemplated by Congress. Their novel approach, which has no support in the text of the statute, could insert rampant gamesmanship and uncertainty into the national pharmaceutical market. The members of AAM therefore have a strong interest in the outcome of this case.

SUMMARY OF ARGUMENT

For nearly two hundred years, the on-sale bar has funneled inventors into the patent system by preventing inventors from commercializing their inventions indefinitely before filing a patent application. By encouraging inventors to file for patents, the on-sale bar promotes disclosure and the "Progress of Science and useful Arts." U.S. Const. art. 1, § 8, cl. 8. At the same time, the rule enforces the constitutional limit that patents be granted for "limited Times." *Id.* Both of these virtues are well-served by the long-settled principle that secret sales—that do not disclose the details of an invention subject to the sale—nevertheless

place the invention "on sale" and thus trigger the statutory clock. *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

Helsinn argues that Congress reversed course in the America Invents Act ("AIA") and lifted the on-sale bar for any sale in which at least one "term" of the sale is not disclosed to the public. Teva has already ably explained why Helsinn's interpretation is foreclosed by the plain text of the on-sale bar and the history of the provision. AAM writes to emphasize the extent to which Helsinn's interpretation (and the government's variant) would invite manipulation and foster confusion in the pharmaceutical market, with deleterious consequences for patients, taxpayers, and others who seek more affordable medicines.

It takes little imagination to see how Helsinn's rule would allow a drug manufacturer to extend the effective life of its monopoly. A manufacturer simply could market the drug through a partially confidential transaction and thereby obtain the benefits of commercialization without starting the clock on its patent rights. Rather than having to choose between commercialization and secrecy, an inventor under Helsinn's rule could have both. That rule would be detrimental in every sector of the economy, but it is particularly pernicious in the context of pharmaceuticals where it prevents the public from obtaining generic medicines long after the patent term should have expired.

The government's proposed variant in which only sales to ultimate customers trigger the bar is equally manipulable. Indeed, in the context of pharmaceuticals,

the government's rule would in almost every case afford a manufacturer the ability to delay seeking a patent because drug manufacturers almost never sell directly to consumers.

Even where Helsinn's rule and the government's variant do not lead to intentional manipulation, they will cloud patent rights by generating significant doubt as to whether sales are or are not invalidating. A generic manufacturer may not always be able to ascertain whether a particular sale is sufficiently confidential to avoid the on-sale bar. This uncertainty would be particularly harmful in the pharmaceutical industry, where both brand-name and generic manufacturers will not make investments unless patent rights are clear.

Helsinn suggests that the time needed to seek FDA approval justifies delaying the patenting requirement. But Congress already took account of that delay when it enacted the patent term extension statute, 35 U.S.C. § 156, which confers an additional period of exclusivity for the time spent awaiting FDA approval. Helsinn's position would allow inventors to "double dip" by commercializing their product while awaiting FDA approval while *also* benefiting from the patent term extension.

Opening patent law to a manipulable rule that engenders uncertainty risks underming a competitive market carefully calibrated by Congress for the past four decades. The on-sale bar's application to sales that are not fully public preserves the public's interest in a market where robust competition ensures better patient outcomes and greater access to life saving medicines. Every year the public is delayed in obtaining generic

medicines means higher pharmaceutical prices and worse patient outcomes. The Court should affirm the Federal Circuit;s interpretation of the on-sale bar and its judgment that Helsinn's '219 patent is invalid because Helsinn placed its invention on sale more than a year before it applied for the patent.

ARGUMENT

AAM agrees with Teva that the on-sale bar means what it has always meant: an item is "on sale" if it is sold or offered for sale from one entity to another, even if details of that sale are confidential. Helsinn does not contest that, despite having ample opportunity to do so, Congress has not tinkered with the text of the on-sale bar itself. Instead, Helsinn and its *amici* ask this Court to jettison nearly two centuries of precedent based on an unassuming residual clause added to the end of § 102(a)(1) by the AIA. But this Court has long held that "modification by implication" of a statute with a "settled construction" is "not favored." *United States v. Madigan*, 300 U.S. 500, 506 (1937). If Congress "intend[ed] to effect a change of that kind," it would have "provide[d] a relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017).

What makes Helsinn's construction of the on-sale bar all the more dubious is that it would frustrate core policies of patent law and their application to the pharmaceutical industry in particular. In enacting both the Patent Act and the Hatch-Waxman Act, Congress struck a delicate balance between innovation on the one hand, and public access to life-enhancing and life-saving

inventions on the other. By allowing commercialization through confidential sales, Helsinn would disrupt this careful balance. Brand-name pharmaceutical companies would have free license to manipulate their commercial activity to extend the duration of their government-sanctioned monopoly (and the profits that go along with it) far beyond that which Congress ever inteded. In the process, these companies would deprive patients of sorely needed low-cost drugs, thereby frustrating one of the main goals of the Hatch-Waxman Act.

By asking this Court to effect a seismic shift in the law from a small change to § 102(a)(1), Helsinn asks the Court to find the proverbial elephant hidden in a mousehole. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). But that is not how statutory construction works. The Court should affirm the Federal Circuit's holding that Helsinn's patent is invalid because Helsinn placed it on sale more than a year prior to filing.

I. Generic And Biosimilar Drug Companies Serve a Critical Role in the Pharmaceutical Marketplace by Providing Affordable Access to Medicines.

Manufacturers of generic drugs have long ensured affordable access to medicines for millions of American consumers. Taxpayers, employers, insurance companies, and state and federal governments have benefited from trillions of dollars in savings from lower-cost alternatives to brand-name medicines.

The United States is a global leader in generic drug use.[2] In 2016, generic drug companies filled 89% of Americans' prescriptions and manufactured over 61 billion prescription doses in the United States.[3] The affordability of generic drugs has led to expanded access to medications that has improved patient outcomes. Experts estimate that half of patients with chronic diseases do not take their medications as prescribed, and non-adherence to prescription drugs accounts for approximately 125,000 deaths annually.[4] Patient abandonment rates for generic medicines, however, are approximately 66% lower than for branded drugs, an unsurprising figure given that 90% of all generic medicines are available to consumers for less than $20.[5]

Not only is the generic marketplace good for patients, but it benefits taxpayers, too. Although brand-

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[2] Olivier J. Wouters, Panos G. Kanavos, & Martin K. Mckee, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending*, 95 Milbank Q. 554, 564 (2017), https://www.milbank.org/wp-content/uploads/2018/01/WOUTERS_et_al-2017-The_Milbank_Quarterly.pdf.

[3] Ass'n for Accessible Medicines, White Paper, *Ensuring the Future of Accessible Medicines in the U.S.*, at 4 (2018), http://accessiblemeds.org/sites/default/files/2018-02/AAM-Whitepaper-Ensuring-Future-of-Generic-Medicines.pdf [hereinafter *Ensuring the Future*]; Ass'n for Accessible Medicines, *Generic Drug Access & Savings in the U.S.*, at 7 (2017), http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf [hereinafter *Savings*].

[4] *Ensuring the Future*, *supra* note 3 at 5.

[5] *Id.*

name drugs account for only 11% of prescriptions dispensed in the U.S., they account for more than 74% of total drug spending. One of the largest subsidizers of prescriptions is the federal government.[6] In 2015, the U.S. government paid roughly 43% of all retail prescription drug costs—29% through Medicare and 10% through Medicaid.[7] Medicare and Medicaid saved $77 billion and $37.9 billion, respectively, in 2016 due to savings associated with lower-cost, generic drug options.[8] This equates to an average annual savings of $1,883 per Medicare enrollee and $512 per Medicaid enrollee.[9] With health expenditures climbing 5.8% in 2015 and accounting for 17.8% of Gross Domestic Product, the savings associated with generic drug options has become an indispensable component of national health policy.[10]

Since the mid-eighties, Congress has prioritized competition in America's prescription drug policy by enacting legislation designed to protect the entry of generic drugs onto the market. One of the primary goals of the Drug Price Competition and Patent Term

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[6] *Savings*, *supra* note 3 at 33.

[7] Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, Brookings Inst. (Apr. 26, 2017), https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/.

[8] *Ensuring the Future*, *supra* note 3 at 6.

[9] *Id.*

[10] *Savings*, *supra* note 3 at 8.

Restoration Act, commonly known as the Hatch-Waxman Act, was to facilitate the entry of generic drugs. The Hatch-Waxman Act not only streamlines the FDA approval process for generic drug applications, but also incentivizes challenges to the validity of brand-name patents by offering a 180-day exclusivity period to generic companies who successfully obtain a court ruling that the brand patent at issue is valid or not infringed.[11]

Congress's foray into prescription drug policy, however, has not deterred anti-competitive practices by brand drug manufacturers. Such manufacturers may engage in a variety of practices known as "evergreening" that seek to extend a drug's period of exclusivity as a means of preventing low-cost alternatives from entering the market. For instance, they may attempt to "patent 'new inventions' that are really just slight modifications of old drugs."[12] Such patents result in fresh 20-year monopolies on drugs that should be in the public domain. Alternatively, manufacturers may take advantage of a provision of the Hatch-Waxman Act staying generic entry for 30 months under certain circumstances, by securing seriatim stays that can delay generic entry indefinitely.[13] Those

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[11] 21 U.S.C. § 355(j)(5)(B)(iv).

[12] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 Can. Med. Ass'n J. E385, E385 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/; *see generally* Scott C. Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327 (2011).

[13] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 711-15 (2009) (explaining this strategy in detail).

practices inhibit innovation and harm the nation's fiscal health.

In this case, Helsinn's position reflects a variation on the evergreening theme: it seeks to obtain monopoly profits for a period exceeding the statutorily prescribed monopoly period. Helsinn's position is inconsistent with the national policy of allowing generic entry after that period has expired to ensure affordable access to drugs.

II. The On-Sale Bar Promotes Disclosure of Inventions by Limiting the Time in Which Inventors Must Seek Patent Protection After They Have Commercialized Their Inventions.

The on-sale bar ensures that patentees can obtain monopoly profits for the statutorily prescribed period—and no longer. This Court has recognized that policy underlying the on-sale bar for nearly two centuries. Treating a secret sale not as a "sale" for purposes of the on-sale bar would violate the on-sale bar's text and frustrate the bar's historic purpose.

A. The On-Sale Bar Has Applied to Confidential Sales for Nearly 200 Years.

This Court recognized nearly 200 years ago that confidential sales invalidate patents in *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 23-24 (1829). In *Pennock*, the Court invalidated the plaintiff's process patent on the grounds that he had made and sold the output of that process (fire hoses) seven years prior to filing his patent application. *Id.* at 9. Although Pennock never disclosed the details of his inventive process, the Court nonetheless held that Pennock forfeited his right to a

patent by engaging in pre-grant sales of the article produced by that process. *Id.* at 23-24.

Justice Story rooted the Court's holding in the constitutional limit that patent monopolies be granted for "limited times." *Id.* at 16. Recognizing the potential for patent owners to extend their lucrative monopolies through such early sales activities, the Court reasoned:

> [i]f an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention[]...and make, and sell his invention publicly, and thus gather the whole profits of it[]...and then only, when the danger of competition should force him to procure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any further use...*it would materially retard the progress of science...and give a premium to those who should be least prompt to communicate their discoveries.*

Id. at 19 (emphasis added).

Congress formally incorporated a prohibition on patenting "on sale" inventions into the Patent Act in 1836. Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119. Although the Patent Act has undergone substantial revisions since 1836, this statutory "on sale" language has survived unchanged. And as recently as 1998, this Court reaffirmed *Pennock*'s holding. *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55, 64 (1998).

B. The Policies Justifying the On-sale Bar Are Served by Treating Confidential Sales as Sales.

In the wake of *Pennock* and the statutory codification of the on-sale bar, courts have identified two primary policies served by this rule. First, the bar "encourages an inventor to enter the patent system promptly." *Woodland Trust*, 148 F.3d at 1370. Second, and relatedly, the bar serves to "prohibit[] the commercial exploitation of [a protected invention] beyond the statutorily prescribed time period." *Cont'l Plastic Containers v. Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).

Using these policies as guideposts, courts have repeatedly endorsed the rule that commercial sales trigger the one-year period to apply for a patent even though some of the details of the sale or the invention may not be public. *See, e.g., Woodland Tr.*, 148 F.3d at 1370 ("Thus an inventor's own prior commercial use, albeit kept secret, may constitute a...sale under § 102(b), barring him from obtaining a patent"); *accord Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001).

The secret sale bar acknowledges that boundless pre-grant commercial activity undermines the constitutional rule that patent monopolies be granted for "limited Times." U.S. Const. art. I, § 8, cl. 8. So long as an inventor can profit from an invention by keeping it secret—without any repercussions with respect to the patentability of that invention—there is little incentive for that inventor to seek out a congressionally mandated term limit to commercial exclusivity. This "premium to

those who should be least prompt to communicate their discoveries" is precisely the objective that the on-sale bar is designed to neutralize. *Pennock*, 27 U.S. at 19.

Moreover, tacking on a government sanctioned monopoly *after* a limitless period of commercial profits presents a problem of constitutional dimension. If a patent owner can effectively extend its exclusivity indefinitely through confidential sales prior to a twenty-year patent term, the patent grant will effectively morph into an infinite monopoly right to those savvy market participants who are able to keep an invention under their confidential control. In the complex commercial marketplace of the 21st century, the virtues of the confidential sales rule continue to apply with equal if not more compelling force.

C. The Policies Underlying the On-Sale Bar Are Consistent with Treating Sales to Distributors as Sales "to the Public."

Of course, the Court cannot resolve this case based on policy alone: the text of the on-sale bar provision is paramount. But the policies underlying the on-sale bar powerfully support Teva's textual argument that Congress did not change the meaning of "on sale" by the oblique mechanism of adding an *additional* category of prior art. Likewise, even if Helsinn and the government are correct that the on-sale bar applies only to "public" sales, the policies underlying the on-sale bar would still inform the interpretation of the word "public." In view of those policies, the Court should hold that any sales that "take place between two separate entities" are sufficient to trigger the on-sale bar. *Special Devices*,

Inc., 270 F.3d at 1356 (internal quotation marks omitted).

Classifying "secret" sales as sales for purposes of the on-sale bar comports with the principle that the Patent Act should be construed in accordance with common-law commercial principles. In *Impression Products, Inc. v. Lexmark International, Inc.* 137 S. Ct. 1523 (2017), this Court held that the "common law's refusal to permit restraints on the alienation of chattels" is incorporated into the Patent Act via the exhaustion doctrine, observing that "[w]here a common-law principle is well established, ... courts may take it as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident." *Id.* at 1536 (quotation marks omitted; alterations in original). Consistent with that principle, the Federal Circuit has held that in determining the question of whether an offer for a sale exists, the question must be "'analyzed under the law of contracts as generally understood'" and "must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.'" *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1373 (Fed. Cir. 2016) (en banc) (citations omitted).

These principles require classifying Helsinn's sale as a "sale" for purposes of the on-sale bar. There is no doubt that Helsinn made a "commercial offer for sale," *Pfaff*, 525 U.S. at 67. Whether the sale was secret or not does not affect whether a sale occurred. By contrast, Helsinn's rule—that a product is not "on sale" unless all aspects of the underlying invention have been publicly disclosed—and the government's rule—that a product is

not "on sale" unless it is on sale *at retail*—have no basis in any commercial principles.

While Helsinn does not clearly recite how its test distinguishes "secret" from public sales, it appears to support a rule in which a sale is not "public" unless all details of the sale are publicized. Such a test is untethered from the on-sale bar's purposes. The purposes of the on-sale bar are to encourage early entry into the patent system and to prevent patent owners from undermining constitutional and statutory term limits—by limiting the benefits associated with commercial activity prior to patenting. Both of these goals are threatened by even a single sale where profit flows from one entity to another, and, therefore, it follows that the on-sale bar rule should apply equally to these transactions. As demonstrated by the sale at issue in this case, a single sale to a single buyer can reward the patent owner with profits to the tune of millions of dollars. Whether these millions are made from a single buyer or a broader group does not matter to the incentive structure contemplated by on-sale bar policies. Rather, it is the exchange of consideration—not the identity of the purchaser—that benefits the patent owner.

The government's proposed rule, that a sale is not to the "public" unless it is to the "ultimate consumer," is equally unmoored to the purpose of the on-sale bar and impractical and confusing to boot. The on-sale bar principle is tied to the incentive structure created by an exchange of benefits—not the identity of the sale partner. Moreover, determining an "ultimate consumer" is fraught with unnecessary difficulties and

creates space for difficult line drawing. Corporate supply chains often rely on wholesalers, distributors, and retailers for their profits. The on-sale bar should not turn on how companies structure their vertical supply relationships.

III. A Narrow On-Sale Bar as Proposed by Helsinn Would Promote Manipulation in the Commercial Drug Market and Disrupt Congress's Carefully Balanced Scheme.

Helsinn and its *amici* contend that the AIA dramatically narrowed the on-sale bar. While Helsinn does not offer a clear articulation of what it means for a sale to be "public," it appears to suggest that a sale is not "public" unless not only the sale itself, but also the details of the invention, are publicly disclosed.[14] This rule would allow patent owners to manipulate the system to reap a windfall from both pre-grant and post-grant exclusivity profits. Moreover, the rule would fundamentally alter the pharmaceutical landscape by extending brand-name drug companies' ability to control the market for life-altering drugs.

A. Under Helsinn's Position, Patent Owners Will Enjoy a Double Benefit During FDA Proceedings.

Helsinn's proposed rule would permit an improper form of "double dipping" by patent owners. Federal

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[14] The United States goes even further, arguing that an invention is "on sale" within the meaning of Section 102(a)(1) only when a product embodying the invention can be purchased by its "expected ultimate customer."

patent law compensates patent owners for the period spent waiting for FDA approval by giving them a patent term extension of up to five years. Under Helsinn's position, however, patent owners could *both* obtain monopoly profits during the period spent waiting for FDA approval *and* obtain the five-year term extension, in contravention of Congress's carefully balanced scheme.

In the Hatch-Waxman Act, Congress enacted a "patent term extension" ("PTE") provision designed to compensate patent owners for certain delays in commercialization due to FDA regulatory proceedings. *See* 35 U.S.C. § 156. The Hatch-Waxman Act contemplates that inventors might obtain patents while FDA proceedings are pending, and therefore effectively lose a portion of their statutory monopoly period. To compensate for the time associated with FDA proceedings, Section 156 provides opportunities for patent owners to extend the term of a patent for up to five years, subject to certain limitations. In order to be eligible for a term extension, the patent holder must apply for PTE within a limited period of time following regulatory approval. Critically, although drug manufacturers routinely obtain multiple patents on the same product, the PTE statute states that "in no event shall more than one patent" be extended for any particular product. 35 U.S.C. § 156(e)(1).

Helsinn's position would allow patent owners to obtain the functional equivalent of patent term extensions for multiple patents that exceed the five-year maximum prescribed by § 156. According to Helsinn, inventors can now engage in limitless pre-grant

commercial sales during the FDA approval process (so long as they keep some measure of their invention secret from the public and/or "ultimate customer"). Thus, if Helsinn prevails, a drug company could commercially market a patented product and therefore exercise a functional monopoly while FDA proceedings are pending, without filing a patent application. Then, 364 days after the FDA approves the product and it goes on sale to the general public, the company could file *multiple* patent applications—thus achieving the functional equivalent of a patent term extension on all of those patents.

Further, the length of that functional patent term extension may well exceed five years. The average time from FDA application to approval of drugs is 12 years.[15] Thus, an inventor may begin commercializing a patent a decade or more before FDA approval. If the inventor waits until 364 days after FDA approval to file the patent application, the inventor would achieve the equivalent of a decade-long patent term extension for multiple patents—in contravention of Congress's considered decision to limit the term of the extension to five years for one patent.

Congress has considered the harm associated with regulatory delay and resolved that issue by compensating patent owners with PTE. Piling on the benefit of pre-grant commercial activity would

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[15] Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, JACC: Basic to Translational Science (Apr. 2016), http://basictranslational.onlinejacc.org/content/1/3/170.

constitute a double benefit that undermines the careful balance achieved by § 156.

B. Helsinn's Rule Would Open the Door to Manipulation by Patent Owners and Yield Particularly Pernicious Consequences for Drug Consumers.

Helsinn's proposed rule would allow brand pharmaceutical companies to obtain monopoly profits for a period far exceeding the statutorily-prescribed period—a result irreconcilable with the purpose of the on-sale bar.

Helsinn contends that a sale is not a "sale" for purposes of the on-sale bar if conducted in secret. If Helsinn's position prevails, patent owners will obtain a windfall: patent owners could tack the profits earned from these secret sales onto a twenty-year term of patent exclusivity. Such a position would effectively extend the patentee's statutory period of monopoly. During the period of secret sales, the inventor would have an effective monopoly on the commercialization of the invention because the invention is by definition novel, and others could not exploit it while it is kept secret. Then, during the patent exclusivity period, the patentee would enjoy a statutory monopoly. That result is irreconcilable with Congress's goal of ensuring that inventors may exercise monopoly rights during the statutorily prescribed period—and no more.

Moreover, Helsinn appears to propose a rule in which patent owners could publicly announce sales without triggering the on-sale bar, so long as they do not reveal the details of the invention themselves. Indeed, under

Helsinn's apparent rule, even if an inventor publicizes *some* details of the invention, it can avoid the on-sale bar merely by not publicizing *every* detail. This case illustrates the point: Helsinn publicized to the world that its agreement with distributor MGI for "palonosetron" was ushering the company into the "$1 billion North American market for 5-HT, antagonists." J.A. at 251-52. The only relevant language redacted from Helsinn's public filings was a description which disclosed the 0.25 mg dosage of the drug, yet Helsinn now contends this redaction allows it to evade the on-sale bar.

By making such announcements, inventors attract follow-on investment and chill competition. Here, for example, Helsinn's announcements put generic firms on notice that another patent may be issuing in the field of 5-HT antagonists, thus deterring those firms from developing such pharmaceuticals. Helsinn was therefore able to profit from its invention as if it possessed monopoly power. By delaying the filing of its patent application until over a year after the announcement, Helsinn improperly extended its monopoly period.

If the Court adopts Helsinn's proposed rule, patent owners will inevitably exploit it. Although the sale between Helsinn and MGI was a single buyer transaction, the narrow on-sale rule proposed by Helsinn places no bounds on the number or volume of transactions that trigger the on-sale bar—only the terms of its secrecy. Sales could conceivably extend to dozens of firms. So long as participants adhere to some measures of confidentiality, patent owners will be in a position to reap substantial benefits.

Not only will extending patent monopolies increase costs during the years of the patentee's improperly-extended monopoly, but it will create the risk of freezing generic drug manufacturers out of the market entirely. The longer the patent term, the more likely that an eventual generic or biosimilar drug will be outdated by the time the patent expires. Longer patent terms can harm patients and our health care system by keeping drug prices high for longer and making it more difficult for competitors to earn a return on investment on drugs that have been superseded. Thus, rigorous adherence to the statutory patent term requirement is necessary to ensure that hospitals and patients can buy generic drugs that are nonetheless state-of-the-art.

Helsinn's proposed rule would also create the risk of a different type of manipulation: the filing and assertion of a new species of "submarine" patents. Submarine patents, or patents that "submerge" during a lengthy prosecution process and then surface after the grant, historically presented a significant disruption to innovators who invested in products with an unknown patent thicket looming in ex parte prosecution proceedings. *See generally Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378 (Fed. Cir. 2005), *amended on reh'g*, 429 F.3d 1051 (Fed. Cir. 2005). The AIA's first-to-file regime, coupled with the modern rule that the statutory period commences as of the date of the patent application (rather than the date the patent is granted), were intended to solve this notorious problem. But abandoning the secret sale rule would reintroduce the same problem in a different form: inventors of

concealable inventions could commercialize their inventions for years or decades before surfacing and filing for patents. Industry participants who independently conceive of the same invention will have relied on the absence of a patent in that market to justify their investment, only to be surprised with infringement claims years later. As Professor Lemley explains:

> Inventors of easily concealable inventions like manufacturing processes could keep their process inventions secret for years or even decades and then surface and file a patent application. Because that application was filed later, the patent would expire later. It could take an existing industry by surprise because others who developed but did not patent the technology would not be able to use their own secret use as prior art to defeat the patent. And while some inventors will not want to take the risk that someone else patents the idea before them, the AIA actually lessens that risk by giving the first inventor a prior user right. [Requiring prompt applications after commercialization] would encourage delay in patenting in the hopes of extending the life of a patent. That is directly contrary to the goals of first inventor to file in the AIA, which encourages early filing of patent applications.

Mark A. Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1132 (2015) (footnotes omitted).

Helsinn maintains that the AIA's shift from a first-to-invent to a first-to-file regime resolves concerns about manipulation. According to Helsinn, an inventor who delays the filing of an application risks losing the patent to another inventor who files first, so there is no risk that an inventor will deliberately delay in filing a patent application. Helsinn's contention ignores the reality of how the pharmaceutical industry actually operates. First, although the AIA enacted a first-to-file regime, it did not eliminate the bedrock rule that only the *inventor* is entitled to a patent. Indeed, it expressly provides that a disclosure in a patent application "shall not be prior art to a claimed invention" if "the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor." 35 U.S.C. § 102(b)(2)(A). And it creates a new procedure known as a "derivation proceeding," which allows a later-filing applicant to obtain a patent by proving that the earlier-filing applicant "derived" the invention from the later-filing applicant. 35 U.S.C. § 135. Thus, so long as an inventor reasonably believes that another person will not independently conceive of the same invention, the inventor can engage in "evergreening" tactics without a risk of losing the right to file an application later.

In the real world, brand-name drug companies can engage in such manipulative tactics without running the risk of losing the right to a patent. As previously noted, a common "evergreening" tactic is to extend a patent on an existing drug by patenting a new means of storage or administration, a slight modification, a new release mechanism, or the like. The "inventors" of such "inventions" will almost invariably be the patentees of

the existing drug: they are the sole entities in a position to conduct the research necessary for these follow-on inventions, given their monopoly over production and distribution of the drug during the statutory period. Blocking patents may restrict researchers' abilities to develop certain drugs, and other researchers may lack the necessary resources for drug development. Patent owners can engage in those manipulative tactics that extend the statutory period regardless of whether there is a first-to-invent or first-to-file regime.

IV. Upending Traditional On-Sale Principles Will Infuse Uncertainty into the Commercial Marketplace for Both Brand-Name and Generic Drug Manufacturers.

Reversing hundreds of years of case law would have profound implications for upsetting consumer norms and corporate business practices. Helsinn's exceedingly thin conception of the on-sale bar—that sales not only need to be public, but need to expose the details of the patented invention in order to constitute prior sale under Section 102(a)(1)—also opens the door to the reinterpretation of other key patent limits grafted from the 1952 Act into the AIA.

Helsinn does not explain what degree of secrecy is required to shield sales from its proposed new rule. Confidentiality agreements come in many forms and, as shown by Helsinn's agreement with MGI, some agreements leave very little information confidential to the transacting parties. Would only certain claim elements need to remain secret to avoid the on-sale bar? Is absolute secrecy required? Moreover, contract interpretation principles such as those that govern

confidentiality agreements generally draw on state-law principles—would a breach of a confidentiality agreement in one state create on-sale bar implications in others? *Cf. Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001) (noting "the importance of having a uniform national rule regarding the on-sale bar").

In addition, because the on-sale bar has, until now, been consistently interpreted to extend to secret commercial sales, a contrary ruling in this case will create uncertainty into related areas of patent law. For instance, the "public use" doctrine has also been interpreted to apply to secret or non-informing uses. *See Egbert v. Lippmann*, 104 U.S. 333, 337-38 (1881) (holding that a claimed corset stay, used once and hidden from public view, invalidated the patent); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 519-20 (2d Cir. 1946). Helsinn's position might unsettle that longstanding rule.

Helsinn's new on-sale rule would also invite uncertainty that would harm both generic and brand-name pharmaceutical companies. Patent litigation is already uncertain: current data shows that the chances of a generic manufacturer prevailing in a Hatch-Waxman suit is close to 50/50.[16] Helsinn's proposed rule would make the situation worse.

Neither generic and biosimilar manufacturers nor brand-name drug companies could reliably predict

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[16] RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), http:// amlawdaily.typepad.com/pharmareport.pdf.

whether a particular sale is secret enough to invalidate a patent. Brand-name companies would be left with an unclear sense of the size of their markets given the potentially invalidating activity they have engaged in for post-AIA inventions. Meanwhile, generic and biosimilar manufacturers would be subject to two layers of uncertainty: factual uncertainty regarding the precise terms of a sale (which it could not learn until discovery) and legal uncertainty regarding how secret an agreement has to be to avoid the on-sale bar. This uncertainty will discourage patent litigation by manufacturers of generic and biosimilar medicines—which Congress sought to encourage in the Hatch-Waxman Act and Biologics Price Competition and Innovation Act—and discourage both investment and competition.

CONCLUSION

The judgment of the Federal Circuit should be affirmed.

Respectfully submitted,

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